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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 552,147	04 19 2000	Abraham Korol	102.3	3491

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04 11 2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/552,147

Applicant(s)

KOROL ET AL.

Examiner

Anne Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,8,9,11-22 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,6,8,9,11-22 and 31-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The cancellation of claims 3, 5, 7 and 10, the amendment of claims 1-2, 4, 6, 8-9 and 11-22, and the addition of new claims 31-40 requested in Paper No. 10, filed 13 November, 2001, have been entered. The abstract of the disclosure and substitute specification submitted with that paper have been entered. Claims 1-2, 4, 6, 8-9, 11-22 and 31-40 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The oath or declaration remains objected to for the reasons stated in the prior Office action because no new Oath or declaration was filed with the response of 13 November, 2001. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.
4. The draftsman has approved the drawings as submitted.

Claim Objections

5. Claims 4, 33 and 40 are objected to because of the following informalities:

In claims 4 and 33 the comma after "solvent" in line 3 should be deleted.

Claim 40 lacks an article before "gene" in line 1.

Claim Rejections - 35 USC § 112

6. Claims 1-2, 4, 6, 8-9, 11-18 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a silicon carbide/pollen-mediated method of transformation of maize, does not reasonably provide enablement for use of that method in all

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sexually-reproducing plants, as stated in the prior Office action for claims 1-18 and 20-22. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments filed 13 November, 2001, have been fully considered but they are not persuasive. Applicant urges that while some plants, like cotton, may be problematic, plant breeders with ordinary skill in the art make crosses routinely and all that would be required to use the claimed method would be optimization of parameters. The Declaration of 13 November, 2001, submitted by inventor Abraham Korol states that transforming tomato and melon by the claimed method only required altering reagent concentrations and that the method was carried out on other plants.

This is not found persuasive because only maize has the silks required for step (g). Even were plants with silks not required, it remains unclear how the taxonomically and structurally divergent gymnosperms could be transformed by such a method. Furthermore, the declaration only provides anecdotal assertions, rather than specific protocols, to demonstrate that the teachings of the instant specification were not substantially modified in their application to other crop species.

7. Claims 1-2, 4, 6, 8-9, 11-22 and 31-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Applicant's arguments filed 13 November, 2001, have been fully considered but they are not persuasive. Applicant urges that the claims have been amended to correct the defects.

This is not found persuasive because numerous new defects were introduced.

Claims 1 and 31 are indefinite for not setting forth any steps involved in the pollination-fecundation process portion of the method. A claim is indefinite where it does not recite any active, positive steps delimiting how this use is actually practiced.

Claims 1 and 31 are indefinite in their recitation of "comprising of a pollination-fecundation process". It is not clear how a method could "comprise of" a process.

In claims 1 and 31 it is not clear if the pollen germination medium used in step (d) is the same pollen germination medium prepared in step (b).

Claims 1 and 31 lack antecedent basis for the limitation "said silicon carbide fibers" in part (d).

Claims 1 and 31 are indefinite for step (f), as step (g) makes no use of the vortexed paste of step (f) and that paste is not used elsewhere in the method.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd.

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App. 1949). In the present instance, claims 2 and 32 recite the broad recitation "1-20 μm in diameter and 1-250 μm in length", and the claim also recites "between 1-2 μm in diameter and 10-80 μm in length" which is the narrower statement of the range/limitation. Claims 6 and 34 recite the broad limitation "about 5%-15% sucrose ... at pH 5.6" and the narrower limitation "15% sucrose ... at pH 5.6".

Claims 4 and 33 lack antecedent basis for the limitation "the solution of silicon carbide fibers" in lines 1-2.

Claims 8 and 35 lack antecedent basis for the limitation "the DNA" in line 1.

Claims 11 and 37 lack antecedent basis for the limitation "the selection of a transformant" in line 1.

Claims 11 and 37 are indefinite for their recitation of "selection ... is performed by using specific cloned selectable markers selected from the group consisting of antibiotic s and herbicides." First, selectable markers are not cloned, although selectable marker genes are. Second, antibiotics and herbicides are not selectable markers or selectable marker genes. Lastly, the claim does not recite how the selectable marker genes are used to select transformants.

Claim 12 lacks antecedent basis for the limitation "said selectable marker having a phenotypic expression" in lines 1-2.

Claim 13 lacks antecedent basis for the limitation "said selectable gene marker" in lines 1-2.

Claims 14-16 and 38-40 lack antecedent basis for the limitation "said selectable marker" in line 1.

In claims 16 and 40, the enzyme should be --phosphinothricin acetyltransferase--

Claim 17 lacks antecedent basis for the limitation "the plants" in line 1.

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Claim 19 lacks antecedent basis for the limitation "said monocot" in line 2.

Claims 18-21 are indefinite in their recitation of the word "includes." It is unclear if this word is intended to be open or closed, or if it intended to further limit the claim.

8. The claims are free of the prior art, given the failure of the prior art to teach pollen mediated transformation of dicots using silicon carbide fibers and given the inherent unpredictability of pollen mediated transformation of dicots or gymnosperms.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
April 8, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

David T. Fox 2.24